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System2



easyTRA

Targeted Risk Assessment

Get Started 2.1

September 2010

TABLE OF CONTENTS

1	INTRODUCTION	3
2	INSTALLATION	4
2.1	Hardware and Software Requirements	4
2.4.2	Hardware Requirements:	4
2.4.2	Software Requirements:	4
2.2	Software Installation	4
3	FUNCTIONS	5
3.1	General	5
	“Standard” Mode	6
4	BASIS FOR EASYTRA RISK ASSESSMENT	10
5	STRUCTURE OF THE INPUT MODULES	12
5.1	Header Data	12
5.2	Physical-Chemical Data	13
5.3	Human Health Assessment Workers	13
5.4.2	Tier 2 Settings	16
5.4	Human Health Assessment Consumer	18
5.4.1	Tier 2 Settings	20
5.4.2	User-Defined PC/AC	21
5.5	Environmental Exposure	22
5.4.2	Tier 3 Assessments	28
6	TRA-REPORT	30

1 Introduction

EasyTRA calculates the risk for human health and environment of a substance use based on substance specific data and exposure estimates as required under REACH. EasyTRA uses a tiered approach known as "Targeted Risk Assessment". Starting with very restrictive default assumptions for exposure calculation, it is possible to modify conditions in several tiers and thereby achieve an approximation to the actual exposure situation.

EasyTRA is based on the ECHA prescribed "Use Descriptor" system in terms of construction and content. This system is currently only available in English; there are no official translations into other official European languages by ECHA as yet.

In order to avoid future compatibility problems with ECHA's systems, the terms used in the EasyTRA use descriptors are available exclusively in English.

Therefore, it is recommended to familiarize yourself with the REACH descriptor system prior to studying the EasyTRA manual. In Chapter D.4.3 of the ECHA "Guidance Information Requirements and Chemicals Safety Assessment (Part D): Exposure Scenario Building", you will find the necessary explanations for the terminology used for the descriptor system in EasyTRA.

EasyTRA uses algorithms on the basis of the latest versions of the ECHA REACH Guidance chapters R12, R13, R14, R15, and R16 (as of March 2010) and EUSES[®]. EasyTRA works in compliance with ECETOC[®] Targeted Risk Assessment 2010 (as of April 2010) for the calculation of worker and consumer exposure and complies with EU TGD 2003 Risk Assessment Spreadsheet Model 1.24a for the calculation of environmental exposure (see ECHA REACH Guidance chapter R16.6.2). EasyTRA delivers results in accordance with these ECHA-accepted simulation tools at the Tier 1 level. Programming errors in ECETOC[®] TRA 2010 (as of April 2010) and known to us have been corrected in EasyTRA. Therefore, occasional deviations in the results generated with ECETOC[®] TRA 2010 (as of April 2010) and those generated with EasyTRA may occur. These known errors are documented accordingly in Appendix III of the EasyTRA report (see chapter 6).

Exposure scenarios for gases . cannot be calculated in EasyTRA.

2 Installation

2.1 Hardware and Software Requirements

2.4.2 Hardware Requirements:

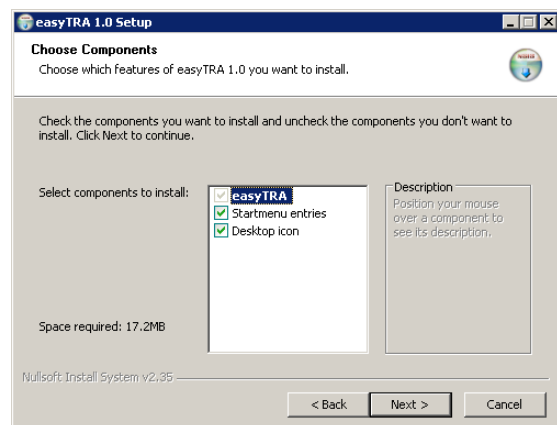
- CPU minimum 2-GHz
- Minimum of 1 GB RAM

2.4.2 Software Requirements:

- Operating system: Windows XP or Linux with 2.6er Kernel
- Java Runtime Environment (JRE) minimum Version 1.6
- For the operation in the “Expert” mode, you will also require:
 - minimum IUCLID 5.2 with installed WebServices (see <http://iuclid.eu> for the installation WebServices)

2.2 Software Installation


After downloading the software installer from the easyTRA website(<http://www.easytra.de>), you can start it immediately via the file setup_easytra.exe. The installer installs the application in a file designated by you and creates a link to the start menu and/or desktop. **In order to use all functions, you must then select a license file under the menu “Tools” -> “Options” as easyTRA will otherwise only run the trial version and will not provide, among others, the “Save” function as well as the “Print” function.**



After the installation has been completed, you can start EasyTRA directly via the created links.

3 Functions

3.1 General

The program contains help texts for many EasyTRA functions. By clicking the question mark symbol , you will access the corresponding help function.

- **Entering Data in Tables**

New data is entered in tables via the last empty line. As soon as data is entered in a line, EasyTRA immediately creates a new empty line for further entries.

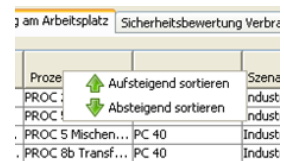
#	Scenario code	Scenariename	Process Category	Type of Setting	Solid	Dustiness during process	Duration of activity [hours/day]	Use of ventilation	Use of respiratory protection	Substance in preparation?
1					<input type="checkbox"/>					

In many columns of a table you can enter identical entries into already existing scenarios by doubleclicking on the grey title field. Entries made into the window, which then opens, will be transferred identically to all scenarios in the individual input masks. In windows with multiple selection options, only those new entries will be attached to or existing entries will be overwritten in all scenarios if they have been selected. All other existing entries remain unchanged. If you would like to only fill in the empty fields in the column with the corresponding entry value, activate the box 'Fill in empty fields only'. Before double-clicking the header line, you may, however, also select one or more scenarios and selectively fill them using the function "overwrite only selected".

Columns which cannot be filled in conjunction with others are dependent upon entries made in other areas of the input module, which is why this function makes no sense in these columns. The columns called "RCR" cannot be actively filled in as these fields are only calculated.

Every column of the tables can be sorted in ascending or declining order by **right-clicking** the mouse on the header line and selecting the direction desired.

You can, however, also move individual scenarios within a table by drag-and-drop.



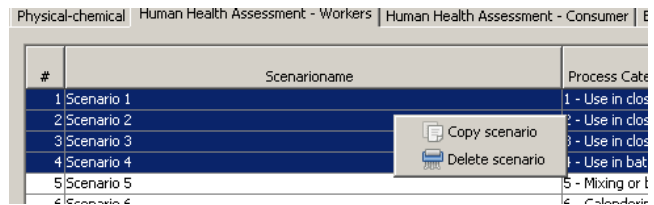
Proze	Szen
PROC 1	indust
PROC 5 Mischen...	PC 40 Indust
PROC 8b Transf...	PC 40 Indust

- **Copying and Deleting Entries**

Every table in EasyTRA provides a "Copy" and "Delete" function via a context menu. Select one or more lines using the cursor and "Shift" key and then right-click the mouse to activate the context menu. The selected lines can now be copied or deleted. Copied lines are automatically entered at the

end of the table and can now be modified. By this method you can create and calculate many different scenarios of similar content in parallel.





You may, of course, copy scenarios with CTRL+c and enter them as copies into the table with CTRL+v. This also functions for copying one or more scenarios from one data set to another, or from EasyTRA to Excel.



If you would like to import entire sets of scenarios from other data records, you can also do this via the "Import" function in the menu "File".

"Standard" Mode

The following functions in the program are available via the menus:

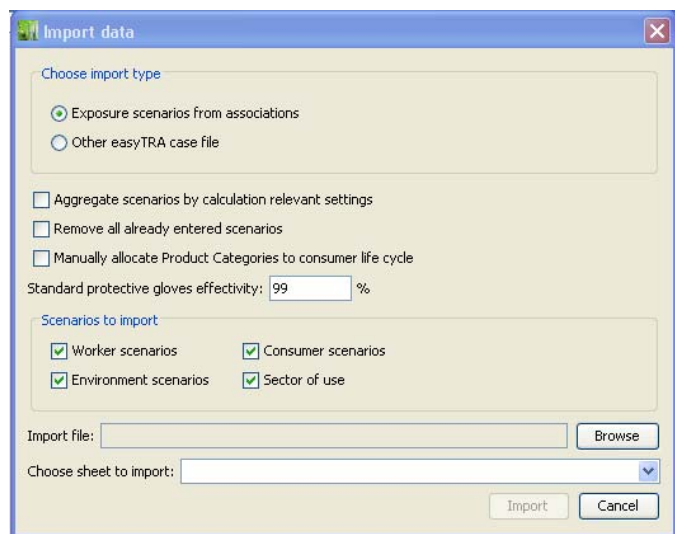
- **File** → **New case** 
 - Creates a new case. The existing entries are deleted and an empty input window is provided.
- **File** → **Open** 
 - Opens an existing TRA file. The current entries are replaced.
- **File** → **Save** 
 - Saves the current case. New cases require new file names.
- **File** → **Save as** 
 - Saves the current case in a new TRA file. The old file remains unchanged.
- **File** → **Import**

To automate the entry of data, data from external sources can be imported.

The source data can be from, e.g. other TRA files. The source data can come from, for example, other EasyTRA files. However, standard scenarios in an Excel format, as provided by several European associations (e.g.

www.duccplatform.org) can also be imported. These must, however, be

available in a fixed format to enable EasyTRA to import them correctly. On the EasyTRA



website (<http://www.easytra.com>) you can download an excel example file in the correct EasyTRA format. This example file can be filled with your own entries or used as a template for the modification of external data records.

When using external data records, ensure that all table headers (as in the example file) are in English and only use EasyTRA compatible selection criteria. If only digits are found in the field “duration and frequency”, they will be evaluated as minutes/day and imported as “Tier 2” “settings (see “Tier 2 Settings”).

The import function enables the aggregation of relevant calculation data in order to minimize the number of of scenarios. In this case, those scenarios, which can only be differentiated by data that is not relevant for calculations, are automatically summarized (e.g. in the case description). All titles of all aggregated scenarios are consolidated in the “description of use” field. **Caution! Do not aggregate scenarios if you intend to export scenarios to IUCLID 5.2 as the titles of environmental scenarios and matching human health scenarios must be identical in order to guarantee correct linking.**

The import function allows you to select the type of scenarios you would like to import: Worker scenarios, Consumer scenarios, Environmental scenarios or a combination of these. If you wish, you can furthermore import the “Sector of Use” (see Chapter 5.1 Header Data) with the scenarios.

When importing Excel files, select the import file via “Browse” and select the data sheet from the excel files that you would like to import. When importing TRA files, you must select the revision from which you would like to import,

If possible, the title of the source file should be English in order to make it possible for third parties to identify the basis for the TRA calculation. All imported Tier 2 settings in the source file are stored in EasyTRA and referenced by naming the source file in the “justification”for Tier 2 changes field. The name of the source file is also transferred to the documentation in the EasyTRA report. Therefore, useful names for the source files are e.g. “AISE consumer exposure scenarios as of March 12 2010.xls“. Additional information on source files and authorship can also however be given (in English) in the “Justification Text for Tier 2 Settings” (see below).

Some industry associations have not included life cycle information to their DUC files as all scenarios refer only to consumer scenarios. If you would not like to add the life cycle information individually to your scenarios later, you can automate the allocation by selecting “manually allocate Product Categories to the life cycle category “Consumer”.

When importing scenarios, you may preset the standard efficacy for gloves for all imported scenarios.

By clicking "Advanced", you can still carry out certain presettings which will simplify the import of several associated scenarios.

▼ Advanced

Advanced import settings

- Enable import of duration of activity as (frequency * duration) (e.g. "2 10" or "2 * 10" -> 20 min)
- "Processing" as default for env. life cycle if missing
- Also accept numerics in descriptor fields (e.g. "8a" -> "PROC 8a")
- Use "Short description of process or activity" as subtitle

Several associations enter exposure duration as a product of frequency and duration. If you activate the corresponding box, EasyTRA multiplies these values in minutes/days directly during import. Information on life cycles in environmental scenarios is often missing in association tables. If you would like to automatically link fields to the life-cycle "Final Use", activate the corresponding box. The box "Numerical Values" can be activated if there are only figures available in the descriptor fields but the descriptor type is missing. This is then added via the corresponding column name by EasyTRA. The last box is activated if you would like to transfer the contents of the column "Short description of process activity" of the DUCC format into the field "Subtitles" of EasyTRA. This enables you to steer the structure of the CSR as "contributing scenarios" in CSR are only bundled via the scenario name but not via the subtitle (see ECHA guidelines for information requirements and substance safety – exposure scenario format D 2.2.2).

A number of product categories (PC) and article categories (AC) are not filed as defaults in EasyTRA. If the box "Import Non-calculable PCs or ACs as User-Defined" is activated, you may later link these categories to your user-defined PCs or ACs.

The justification text entered into the field is used for all Tier 2 justifications which are used by the imported data set, and this information is also used in both the CSR and EasyTRA report. As the working language of ECHA (and therefore the CSR) is English, you must also write the justification text in English. It is highly recommended to enter exact source information into this field to enable the Evaluator of your dossier to verify it. Sensible information in this field are, e.g.: the exact title of the source file and the date of entry of the source file. You may, however, also choose different helpful justification texts.

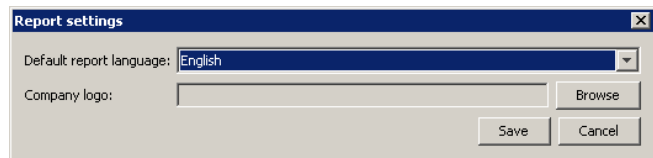
- **Report → Generate Report** 


Calculates the entered scenarios and generates a TRA Report with the results, corresponding entry data and defaults as well as the formulas used for the calculations. The report can be printed immediately or saved as a PDF file (see Chapter 6 TRA Report).

- **Report → Report Settings** 

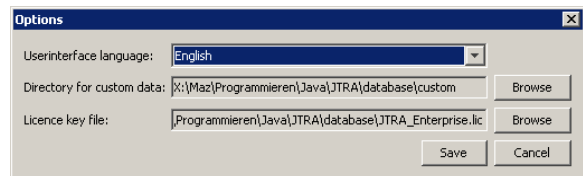
Sets the output language for reports.

The output language is independent of the language setting of the user interface. It is also possible to specify a company logo to be printed on the report header.



- **Tools → Options** 

Via this menu, you can select the language of the user interface, links to the used license file and (depending on the license) the link to the permanent directory for user-defined data.



- **View**

EasyTRA enables the view and entry of number values in decimal formats (e.g. 0.04) as well as in scientific formats (4E-2). In the menu "View", you can alternate between these two View/Entry formats.

The simultaneous calculation of the risk characterization ratio can also be activated or deactivated in the menu "View".

4 Basis for EasyTRA Risk Assessment

EasyTRA calculates the risk of substance usage for humans and the environment on the basis of a comparison of reference values such as Derived No Effect Levels (DNEL) and Predicted No Effect Concentrations (PNEC) and the corresponding exposure scenarios for humans and the environment, which are deduced from the selected exposure scenarios. While the reference values are defined characteristics of the substance to be assessed, the exposure scenarios can be modified within the scope of possibilities in EasyTRA. EasyTRA makes use of a two-step approach.

The first step (Tier 1) involves using very conservative accepted defaults (TRA default values), which have been agreed upon by ECHA, the European chemical industry and the EU member states. EasyTRA uses algorithms on the basis of the latest versions of the ECHA REACH Guidance chapters R12, R14, R15, and R16 (as of March 2010) and EUSES[®]. EasyTRA works in compliance with ECETOC[®] Targeted Risk Assessment 2010 (as of April 2010) for the calculation of worker and consumer exposure and complies with EU TGD 2003 Risk Assessment Spreadsheet Model 1.24a for the calculation of environmental exposure (see ECHA REACH Guidance chapter R16.6.2). EasyTRA delivers results in accordance with these ECHA-accepted simulation programs at Tier 1 level. Programming errors in ECETOC[®] TRA 2010 (as of April 2010) known to us have been corrected in EasyTRA. Therefore, occasional deviations in the results generated with ECETOC[®] TRA 2010 and those generated with EasyTRA may occur. The errors known to us are documented accordingly in Appendix III of the EasyTRA report (see chapter 6).

These Tier 1 defaults may possibly be too restrictive in practice or for your special exposure scenario. For these reasons, EasyTra enables the refinement of the accepted defaults for realistic exposures in a second step (Tier 2), or for further refinement, Tier 3 (currently only available for environmental assessment).

The following will describe the data necessary for a calculation in Tier 1 TRA and the available modification options in Tier 2 or Tier 3 of the input module.

It is recommended that you familiarize yourself with the REACH use descriptor system before entering scenarios in EasyTRA. In Chapter D.4.3 of ECHA's "Guidance Information Requirements and Chemical Safety Assessment (Part D): Exposure Scenario Building", you will find the necessary explanations of the terminology used in the descriptor system in EasyTRA.

The starting point for the calculation of exposure scenarios should always be typical application conditions and not extreme cases. It is important that the application be “identified” in the appendix of the safety data sheet (Article 31 REACH Regulations), which is only possible if the application is safe. You can identify safe applications as the fields in the “RCR” columns for the individual compartments/routes are highlighted in green “RCR” stands for Risk Characterization Ratio and refers to the ratio of the daily dosage/concentration and the actual exposure of a substance.

If, in a given case, a downstream user makes use of your substance under extreme boundary conditions that deviate from your TRA application conditions in one or more points, the downstream user may calculate his own scenario using his own extreme case (Article 37 REACH Regulations). Should the extreme case remain safe, the downstream user must only document this (e.g. with EasyTRA) and has no further obligations. This is, however, only possible if the use is identified in the extended safety data sheet. If the use is not identified, the downstream user has no alternative but to ask the producer to enter his scenario in the extended data safety sheet, and he must calculate the scenario completely on his own and must officially inform ECHA. It is, therefore, in the interest of the producer to identify as many uses as possible.

It is recommended to use the English language for exposure titles and all free texts, such as justifications for the deviation from default assumptions if you intend to generate chapters 9 and 10 of the Chemical Safety Report (CSR) with EasyTRA. According to ECHA, Chemical Safety Reports must be submitted to ECHA in English.

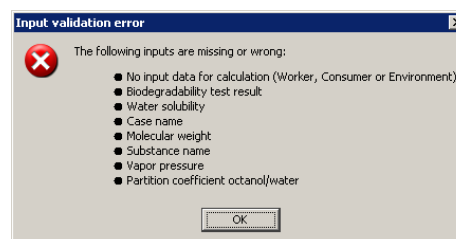
5 Structure of the Input Modules

The input module comprises a total of 5 input masks: Header data, physical-chemical characteristics, worker exposure, consumer exposure and environmental exposure, which can be found under the corresponding tabs. In the following chapters, you will find information on the data you can enter in the input masks and how this will influence the individual risk calculation.

Data fields that are required for the risk calculation are highlighted in yellow.

A TRA Report can only be generated if the yellow fields are filled in.

Depending on the scenarios to be calculated, additional data may be necessary. Should any of this data be overlooked, a message will automatically appear and the program will request you to fill in the missing data.



At the same time, the incomplete data field will be highlighted in red.

All the data entered in the input modules is output in the TRA Report (see Chapter 6) and enables the reader to reconstruct every step.

5.1 Header Data

Header data identifies the substance to be assessed. In the “General Description” field you can enter a free text which you find appropriate. In the “Substance Name” field you must identify the substance. It is recommended to enter further indicative references in addition to the name, such as CAS numbers and EC numbers (EINECS).

The “Sector of Use” is data derived from the ECHA “Guidance Information

Requirements and Chemicals Safety Assessment (Part D): Exposure Scenario Building”. It describes

the relevant industrial sector for your exposure scenario. You can select a single sector or also several sectors, depending on the extent to which your substance is used. The sector of use plays no role in the assessment but the data may help you to maintain an overview.

The “General Description” field offers you the opportunity to enter further information to describe the case.

5.2 Physical-Chemical Data

The input mask “Physical-Chemical” requires the following data:

- Molecular weight
- Vapor pressure
- Water solubility
- Partition coefficient octanol/water

The correct units must be observed when entering the information. For very small or very large values, a scientific input format (see Chapter 3.2 “Standard Functions”) is recommended. Maintaining all “voluntary” parameters in the header data is also recommended as unfavorable defaults may otherwise be made by the system.

Vapor pressure for solids must also be entered.

Physical-Chemical properties

Molecular weight:	<input type="text"/>	g/mol
Vapour pressure:	<input type="text"/>	Pa
Water solubility:	<input type="text"/>	mg/L
Partition coefficient octanol/water:	<input type="text"/>	Kow
Chemical class for Koc-QSAR:	<input type="text"/>	
Koc:	<input type="text"/>	Koc
Partition coefficient $k_{\text{soil/water}}$:	<input type="text"/>	L/kg
Partition coefficient $k_{\text{sediment/water}}$:	<input type="text"/>	L/kg
Partition coefficient to suspended solids:	<input type="text"/>	L/kg

For non-volatile substances without measured values, the value 0.00001 Pa may be entered. The zero value is not permitted.

5.3 Human Health Assessment Workers

The input mask “Human Health Assessment Workers” enables you to calculate a worker’s exposure during work with the help of simple defaults.

Select the most descriptive name possible for your scenario under “Scenario name”. The number of scenarios can become quite large in time, which may make it difficult for you to maintain an overview. The “Scenario Code” can also be of help as there scenario codes available in many associated

scenarios. If associated scenarios are imported using a code, the field will be filled automatically (see chapter 3.1).

#	Scenario code	Scenarioname	Process Category	Type of Setting	Solid	Dustiness during process	Duration of activity [hours/day]	Use of ventilation	Use of respiratory protection	Substance in preparation?
1					<input type="checkbox"/>					

The “Subtitle” are especially suited to differentiate between various scenarios or so-called “contributing scenarios” (see chapter 5.6). While the superordinate environment scenarios are linked via the worker scenarios using the same name and therefore fulfill an important function in EasyTRA, the subtitles serve to enable a clear and distinct description of a scenario.

In Chapter D.4.3 of the ECHA “Guidance Information Requirements and Chemicals Safety Assessment (Part D): Exposure Scenario Building”, you will find the necessary explanations for the term “Process Category. As there are currently no official translations of process categories, these are currently only available in English in EasyTRA.

This mainly deals with a categorized description of industrial and professional processes which cover all defaults. Select a process category which best describes your substance use (e.g. “Used in a Closed Process, No Likelihood of Exposure”). In rare cases, your special application may not be available as a process category. If none of the available categories are appropriate for your application, it may not be possible to calculate this process category with EasyTRA.

Under “Type of Setting”, you can choose whether the application takes place in either the professional or industrial sector. This setting will have an effect upon the exposure defaults.

In the case of a solid substance, the checkbox “Solid” must be selected, and then the grade of dustiness during processing must be entered. The dustiness is subdivided into three general categories that are classified as follows:

Dustiness During Process	Examples
Low	Pellets, Granulate
Medium	Sugar, Salt
High	Flour, Talcum

When in doubt, select the dustier category for your substance.

The grade of dustiness directly affects inhaled and dermal exposure. To minimize the exposure to solid substances, for example, ventilation, respiratory protection and/or the use of gloves can be included (Tier 2, see below).

The duration of the activity is also categorized:

Duration of the Activity	Underlying Factor (Default Setting)
> 4 Hours	8 Hours
1-4 Hours	4.8 Hours
15 Minutes - 1 Hour	1.6 Hours
< 15 Minutes	0.8 Hours

To begin with, the typical duration of the activity and not the extreme case should always be selected, as additional safety factors are already saved in the standard algorithms for the activity duration.

Three different scenarios can be selected in the “Use of Ventilation” field:

- Outdoors
- Indoors without LEV
- Indoors with LEV

These scenarios are based on certain defaults. Modification (Tier 2) has not been provided for at present.

Two different effectivity percentages can be selected in the “Use of Respiratory Protection” field; either 90% or 95% efficiency. The efficiency is then directly integrated into the TRA exposure calculation.

“Substance in Preparation?” is standardly subdivided into 4 categories:

Category	Underlying Factor (Default Setting)
<1%	10%
1-5%	20%
5-25%	60%
> 25%	100%

These categories for the assessment of raw materials in which a certain amount of flexibility is given in the selection of formulas, should normally suffice. If you would like to enter a specific application concentration for your special application instead of the category’s standard options, you can have the modified scenario calculated by “Tier 2” (see next chapter) under certain circumstances..

When you evaluate a solid, the function “Substance in Preparation?” is standardly disabled. However, you can also enter formula data for solids in the “Tier 2” module and have it calculated.

Mandatory fields in the input mask “Workers” are reference values on whose

Manual entry of indicative reference values		Basis of reference value	
Reference value inhalation:	<input type="text" value=""/>	mg/m ³	<input type="text" value=""/>
Reference value dermal:	<input type="text" value=""/>	mg/kg/day	<input type="text" value=""/>

basis the workplace exposure is calculated. Reference values are normally DNELs on the basis of

animal test data (Chapter B7 ECHA Guidance on Information Requirements and Chemical Safety Assessment Part B: Hazard Assessment). EasyTRA also enables the selection of other reference values, e.g. on the basis of existing legal occupational exposure limit values (OELV). In TRA calculations, every entered value is included and documented in the TRA Report. This provides third parties with optimal traceability of the assessment.

Please ensure that the correct reference units for inhalation are selected.


As it can be assumed that no intentional or foreseeable oral exposure at the workplace occurs, the risk assessment of the workplace thus requires no oral reference value.

You can identify safe applications as the fields in the “RCR” columns for the individual compartments/routes are highlighted in green “RCR” stands for Risk Characterization Ratio and refers to the ratio of the daily dosage/concentration and the actual exposure of a substance. These fields are calculated simultaneously as soon as you enter the minimum required data for the scenario. If the fields are highlighted in red, your scenario is not safe according to the selected conditions and you must either set Tier 2 conditions (see chapter 5.3.1) or the scenario in CSR cannot be designated as safe.

Please observe that EasyTRA creates the total risk characterization ratio, RCR, from the sum of RCR_{dermal} and $RCR_{\text{inhalation}}$. This calculation method complies with the ECHA “Guidance on information requirements and chemical safety assessment Appendix to Part F: SR Template” but deviates from the algorithm that ECETOC TRA uses. The results of EasyTRA and ECETOC TRA are therefore not identical here.

RCR dermal	RCR inhal	RCR total
0,01	0,01	0,02
0,27	5,4E-3	0,28
0,03	0,01	0,04
0,07	5,4E-4	0,07

5.4.2 Tier 2 Settings

The button  can be found at the end of every line of the “Workers” input mask. This button only appears if at least one field of the scenario has been filled in. In order to carry out a Tier 2 calculation which deviates from defaults, a further input field can be opened with the help of this button. If the Tier 2 settings have been activated, the button will turn red to make it visible directly in the scenario overview.

After activating the box “Enable Tier 2 Extensions”, specific data can now be entered regarding the use of gloves, the exact duration of activity and the concentration of the substance in preparation. In Tier 2, the standardly blocked input of concentration of the substance in preparation for solids can be overwritten with this module.

The button “Use of Protective Gloves” must be selected if the use of protective gloves is to be taken into consideration. Therefore, the burst time of the glove material must be entered. The module assumes that protection is 99% until the burst time is reached and there is no protection afterwards. Ideally, the burst time and duration of the activity should therefore be identical. You can modify the effectivity of the gloves when necessary.

The function “Substance in Preparation, Exact Value, Inhalation” replaces the standard concentration from the concentration categories (< 1%, 1-5%, 5-25%, >25%) for the calculation of the exposure scenario by the entered value here. EasyTRA standardly makes calculations using higher concentrations than expected under the assignment of the respective category. If, for example, the category >25% is selected, the calculation for the inhalation exposure is, in reality, calculated using 100% (see Chapter 5.3). This deviation is justified by the nonlinearity between the concentration in a solution and the corresponding concentration in the respiratory air. The excessive standard values are, however, only conventional and are not individually calculated thermodynamically as very many influencing factors must be taken into consideration. Therefore if the function “Substance in Preparation, Exact Value, Inhalation” is used, you must scientifically justify why your substance deviates from the default in preparation. A justification could, for example, be that it is a solid for which, of course, vapor pressure laws for liquids do not apply. A list of defaults for each concentration category can be found in Chapter 5.3.

The “Duration of Activity, Exact Value” button enables deviations from the rigid categories in Tier 1. In this case, the values for the average duration of the activity should be entered and not extreme values. If the activity does not take place on a daily basis, the data is averaged according to the total number of working days (e.g. 1 x per month for 10 minutes = 1/20 x 10 minutes = 0.5 minutes/day).

You may also freely define specific risk management measures that are not covered by the standard modifications. In this case the efficiency of the measures must be defined route-by-route (dermal, inhalative).

On the Tier 1 level, EasyTRA does not take into account that the concentration of the substance in preparation substantially influences the dermal exposure. If you would like to take the concentration influence into account in deviation from Tier 1 defaults, activate the button “Max. concentration in preparation considerations also for dermal exposure” Then the upper threshold value for the selected category will be taken into account in the calculation (e.g. selecting 5-25% will take the value 25% into account or selecting >25% will take the value 100%). If you know even more exact maximum concentrations for your preparation, you can enter these in the following field: “Substance in Preparation, exact value “dermal”.

These deviations from Tier 1 defaults are noted in the EasyTRA report , and the deviating algorithms for calculations are documented.

Important: As deviations from the defaults, which have agreed upon between ECHA, EU member states and the industry, occur in Tier 2, a justification must be saved as to why the use of Tier 2 standards are possible in this case. This justification is also output in the TRA report and CSR and is a part of the required documentation. **Therefore please only use the English language in this field.** The justifications for the various Tier-2 measures are distributed among different tabs.

5.4 Human Health Assessment Consumer

The input mask “Human Health Assessment-Consumer” enables the calculation of consumer exposure to products and articles with the help of simple defaults.

#	Scenario code	Scenarioname	PC/AC	Product/Article category	Subcategory	Is product a spray	Amount of product used per application (g)	Product ingredient fraction by weight (%)	Skin surface area - dermal	Skin surface area - oral
1						<input type="checkbox"/>				

Select the most descriptive name possible for your scenario under “Scenario name” The “Scenario Code” can also be of help as there are scenario codes available in many associated scenarios. If associated scenarios are imported using a code, the field will be filled automatically (see chapter 3.1).

The “Subtitle” is especially suited to differentiate between various scenarios or so-called “contributing scenarios” (see chapter 5.6). While the superordinate environment scenarios are linked via the worker scenarios using the same name and therefore fulfill an important function in EasyTRA, the subtitles serve to enable a clear and distinct description of a scenario.

In Chapter D.4.3 of the ECHA “Guidance Information Requirements and Chemicals Safety Assessment (Part D): Exposure Scenario Building” you will find the necessary explanations for the terminology “Product Category” (PC) and “Article Category” (AC).

For the most part, this deals with a categorized description of consumer products and use. The selection is limited as not every possible consumer product is included in the catalogue and not all the listed entries in the ECHA Guidance Document have standardized exposure scenarios in TRA Tier 1. In the product or article category, the category is selected that best describes the substance use. Subcategories enable you to enter more detailed information for the actual application.

If none of the listed entries describe your substance use appropriately, select “Others” in the product/article category and, if necessary, set up a specific scenario in Tier 2.

If the product is a spray, activate the button “Is Product a Spray”. **Note:** Spray applications have a strong effect on inhalation exposure and, measures for respiratory protection are not provided for in EasyTRA. Therefore, according to EasyTRA, in individual cases unsafe spray applications require a detailed calculation by a specialist.

In “Amount of Product Used per Application”, the typical amount of the substance used per application must be entered in grams. This data is optional. If the field is not filled in, a default value is used, should it be stored in Tier 1. The default values are output in the report to guarantee the transparency of the calculation.

In “Product Ingredient Fraction by Weight” the percentage of the substance in the consumer product must be entered. This data is optional and will possibly be replaced by a default value, should it be stored in Tier 1. The default values are also output in the report.

In “Skin Surface Area - Dermal” and “Skin Surface Area – Oral”, it is possible to specifically enter which body surfaces are exposed to the consumer product in individual cases. “Skin Surface Area – Dermal” applies to scenarios with adults while “Skin Surface Area – Oral” applies to infants. Not every consumer product is, therefore, applicable for both parameters. This data is also optional and will be replaced by default values

in the calculations, should they be stored in Tier 1.


For the reference values

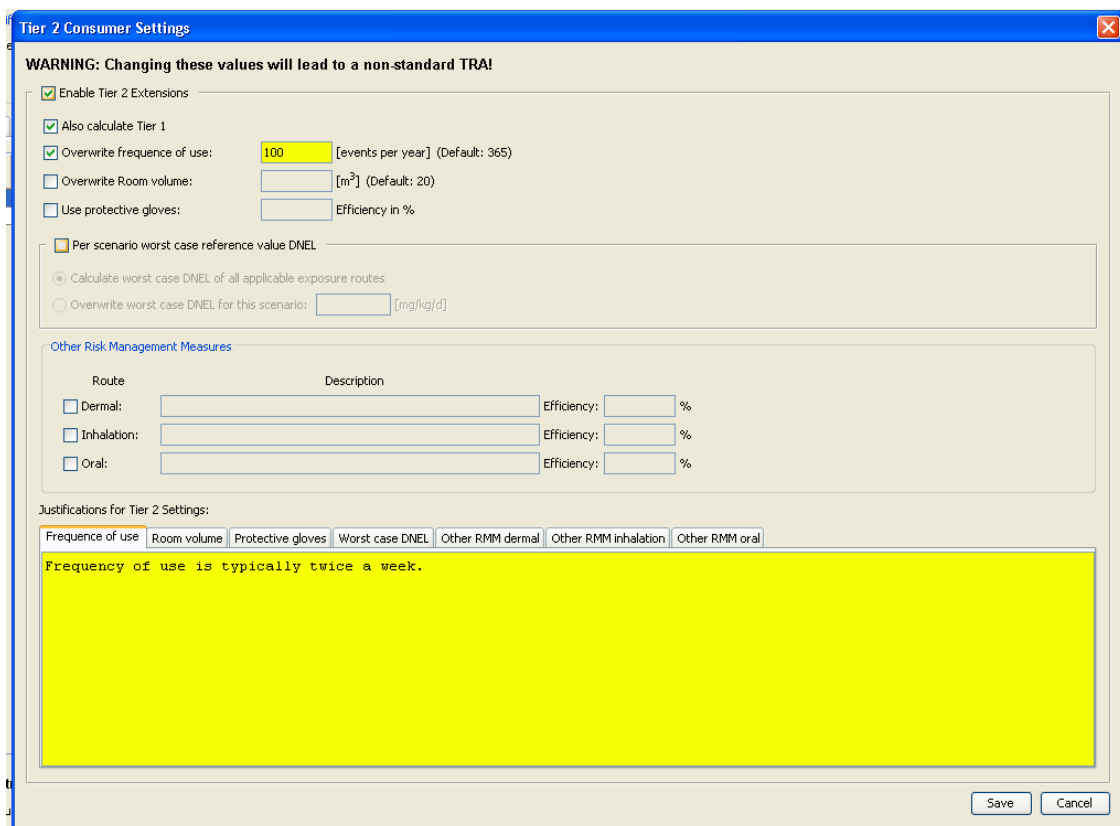
Manual entry of indicative reference values		Basis of reference value	
Reference value inhalation:	<input type="text"/> mg/m ³	<input type="text"/>	<input type="text"/>
Reference value dermal:	<input type="text"/> mg/kg/day	<input type="text"/>	<input type="text"/>
Reference value oral:	<input type="text"/> mg/kg/day	<input type="text"/>	<input type="text"/>
Reference value worst case:	<input type="text"/> mg/kg/day	<input type="text"/>	<input type="text"/>

the same fundamentally applies as already described in the worker exposure section. In addition to the reference values for inhalation and dermal exposure, the oral route is also taken into consideration in consumer use.

Please observe that EasyTRA creates the total risk characterization ratio, RCR_{total} , from the sum of RCR_{dermal} , RCR_{oral} and $RCR_{inhalation}$. This calculation method complies with the ECHA “Guidance on information requirements and chemical safety assessment Appendix to Part F:CSR Template” but deviates from the algorithm that ECETOC TRA uses. The results of EasyTRA and ECETOC TRA are therefore not identical here.

5.4.1 Tier 2 Settings

The button  can be found at the end of every line of the “Consumer” input mask. This button only appears if at least one field of the scenario has been filled in. In order to carry out a Tier 2 calculation which deviates from defaults, a further input field can be opened with the help of this button. If the Tier 2 settings have been activated, the button will turn red to make it visible directly in the scenario overview.



Tier 2 Consumer Settings

WARNING: Changing these values will lead to a non-standard TRA!

Enable Tier 2 Extensions

Also calculate Tier 1

Overwrite frequency of use: [events per year] (Default: 365)

Overwrite Room volume: [m³] (Default: 20)

Use protective gloves: Efficiency in %

Per scenario worst case reference value DNEL

Calculate worst case DNEL of all applicable exposure routes

Overwrite worst case DNEL for this scenario: [mg/kg/d]

Other Risk Management Measures

Route	Description	Efficiency: %
<input type="checkbox"/> Dermal:	<input type="text"/>	<input type="text"/> %
<input type="checkbox"/> Inhalation:	<input type="text"/>	<input type="text"/> %
<input type="checkbox"/> Oral:	<input type="text"/>	<input type="text"/> %

Justifications for Tier 2 Settings:

Frequency of use | Room volume | Protective gloves | Worst case DNEL | Other RMM dermal | Other RMM inhalation | Other RMM oral

Frequency of use is typically twice a week.

Save Cancel

After activating “Activate Tier 2 Extensions” on the Tier 2 level, consumer exposure settings regarding the frequency of use of the product, use of protective gloves and the room volume can be changed. Further specific risk management measures can also be taken into account, whose efficiency per route can be freely defined.

Irrespective of the information you have entered in the corresponding fields of the input mask, standard values for certain products or article categories are filed for the product volume used and the exposed skin surface. If you would like to calculate the exposure in deviation from the standard values, you must activate the box “Enable overwrite of standard values”.

Important: As deviations from the defaults, which have agreed upon between ECHA, EU member states and the industry, occur in Tier 2, a justification must be saved as to why the use of Tier 2 standards are possible in this case. This justification is also output in the TRA report and CSR and is a part of the required documentation. **Therefore please only use the English language in this field.** Note, that the justifications for the various Tier-2 measures are distributed among different tabs.

5.4.2 User-Defined PC/AC

A number of product and article categories (PC/AC) cannot be automatically calculated as there are no filed values with regard to the standard settings. On the EU level there has, as yet, been no coordination of these categories, and you must therefore possibly define the standard values yourself. First, select “User-defined Product and Article Categories” via “Options” in the Header.

Short name	Description	Related PC/AC	Route Inhal	Route dermal	Route Oral	Frequency of use [events / year]	Exposure time [h]	DEFAULT Skin surface area - dermal	DEFAULT Skin surface area - oral	Layer thickness [cm]	Volume swallowed [cm3]
PC 6 cons...	Automotive Care Products (consumer use)	PC 6 A...	Adult	Adult	Adult	50	0.5	hands and fore...	fingers one hand	1	

Now enter the short name, description and the assigned PC or AC category. In the description, justify the exposure conditions you will use in the following fields. Please use the English language as the justification will be included in the CSR and must therefore be submitted in English.

The information regarding the exposure route refers to either adults or children and is mandatory along with the frequency of use and exposure time. If no exposure occurs in a route, select “None”. The contact surfaces of the skin are subdivided into dermal and oral exposures. The oral exposure only applies to children, who, for example, stick their fingers in their mouths after touching an article. Depending on the selected combination, you must either prescribe the layer thickness of the substance on the skin (adults) or a volume of swallowed substance (only children). As a point of reference, the EasyTRA standard layer thicknesses, which are between 0.01cm (e.g. for washing and

cleaning agents or wall paints) and 0.001cm (e.g. for furniture, plastic articles or shoes) can be used. The values filed for a swallowed volume for children are currently between 1.35g for finger paints and 0.001g for toys. If you can verify more realistic values, you may include them accordingly in EasyTRA for calculations.

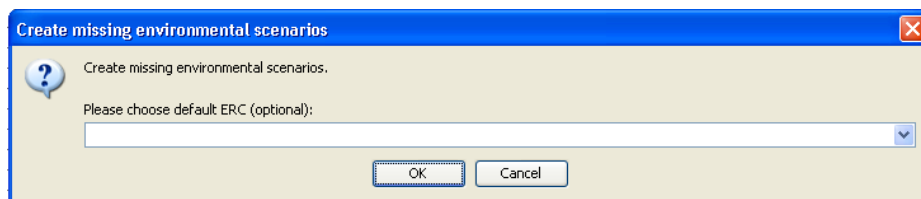
5.5 Environmental Exposure

The input mask “Environmental Assessment” enables the calculation of environmental exposures by manufacturing, processing and final use of the substance with the help of simple defaults. However, environmental exposure differs from human exposure fundamentally, as the production volume or the volume of use plays a decisive role. (Input field “Tonnage”).

#	Scenario code	Description of use	Lifecycle stage	Tonnage	Fraction of tonnage to region	ERC	spERC Industry sector	STP	spERC
1								<input type="checkbox"/>	

Every consumer or worker scenario must always also be assigned an environmental scenario. The assignment is carried out via an identical scenario name. If you would to differentiate between scenario versions or contributing scenarios by title, please select only the subtitle in the category “Worker” or “Consumer”.

To automatically create a missing environmental scenario for an existing consumer or worker scenario, select the scenario and right-click the mouse. In “Create Missing Environmental Scenario”, EasyTRA generates a new environmental scenario with the same title. This serves to avoid a wrong assignment due to a spelling error in the title.



While automatically generating environmental scenarios, you can also already assign a common ERC for all newly generated scenarios.

EasyTRA only generates environmental scenarios for your selected worker/consumer scenarios within the scope of this automatic function if no corresponding ones exist.

First, select the most descriptive name possible for your scenario in “Description of Use”. Many industrial associations (e.g. AISE, COLIPA) have already put lists of standardized scenarios on the Internet. EasyTRA supports these standardized scenarios via the import function (see Chapter 0) which will also import the “Scenario code” if provided.

In the column "Lifecycle Stage", the stage of the product lifecycle to be assessed must be entered. EasyTRA allows you to enter any number of scenarios at this point. A registration dossier will usually cover the complete product lifecycle, i.e. manufacture, processing, final application and waste. In accordance with REACH, the stages are defined as follows:

- Manufacturing of substances
- Manufacturing of preparations, formulations
- Final use, industrial, professional or by the consumer
- Intentional release of substances from products
- Waste stage

If the (raw material) manufacturing process should be viewed, select "Manufacturing". The mixture of the raw material in a manufacturer's or downstream user's formulation falls under the term "Formulation". When selecting the lifecycle stage, please ensure that you comply with the REACH definition; otherwise, further descriptions of environmental scenarios can lead to incorrect assignment of release volumes.

The decisive question in environmental risk assessment is whether the environmental entry by final users is carried out via a "point source" or "wide dispersive" distribution. Point source entries normally lead to more critical assessments due to higher local concentrations.

The term "Service life" describes the use of substances in products from which the substances are intentionally released during use. A typical example of this is pigments in printer cartridges. Emissions which are generated during the waste stage of a substance are dealt with in "Waste Stage". For substances which are used in products and which discharge effluents in accordance with the regulations, e.g. cosmetics, washing and cleaning products, the disposal is already included in the calculation if the Environmental Release Category (see ERC "Wide Dispersive Use" below) has been correctly assigned and must therefore not be taken into special consideration.

In the column "Tonnage", the amount of the substance must be entered for the according scenario. In the following, you will find several examples:

- "Manufacturing": The annual total manufacturing volume of a company at the biggest site in Europe.
- "Formulation": The annual total processed volume in the plant of formulation
- "Final Use" for consumer use is, strictly speaking, only the cumulated total annual volume of the individual manufacturer which is used for the specific application. If data is available, the cumulated total annual volume (for this application) of all European manufacturers and importers can be included in the underlying assessment. It is useful to include which of

both variations the scenario refers to in the title of the scenario, as ECHA may possibly sum up the individual volumes of manufacturers and importers.

- "Final Use" for final industrial use. The total annual volume that the (largest) user uses in his plant.
- "Final Use" for final professional use. "Tonnage" is the total annual volume which is continentally used for this scenario.

It is also very important to select the correct reference under "Tonnage" to achieve realistic assumptions.

The field "Regional Tonnage" enables you to either assign 100% or only 10% of the total tonnage to an individual standard region (approx. 4000 km²). This data simulates the regional dilution effect for substances, which are not discharged at only one point in the environment. For industrial use, it is standardly assumed that there is only one plant as an emission source (factor 100%). The application of the standardized 10% rule is only possible for the steps "Formulation" and "Final Use" if it is sure that there is a corresponding homogeneous distribution of emission sources throughout Europe, i.e. if there are relatively many small or medium-sized customers with a wide regional distribution or if it involves consumer products with Europe-wide sales.

In the field "Scenario Type" the assessment is selected that is either supported by a generic scenario (e.g. an ERC) or a specific scenario (spERC). The ERCs are usually calculations in Tier 1 while spERCs indicate the Tier 2 level. spERCs should be used wherever possible as they represent significantly more realistic conditions. It is therefore necessary to determine whether the corresponding industrial associations have published spERCs in the meantime.

About 120 scenarios are currently stored (as of 1 February 2010) in the field "spERC Industry Sector". Industrial scenarios can be distinguished in that they are standardly connected with point source environmental emissions. Professional and consumer scenarios in the ERC system can be recognized by the term "wide dispersive use" and are calculated on the basis of areawide environmental exposure.

Only ERC1 can be selected in Tier 1 for the production of raw materials. The production of formulations is only depicted as ERC2 or ERC3 in Tier 1. Normally, the corresponding assignments of the ERCs regarding the relevant use have already been made available by industrial associations ("Description of use"). For many scenarios, however, industrial associations have also developed specific ERCs (spERCs), which are stored in EasyTRA and are available in the field "spERC". spERCs are defaults on the Tier 2 level.

Association-specific spERC scenarios can only be loaded if

- 1) first, the corresponding generic ERC scenario has been selected

- 2) the relevant industrial sector in the field "spERC Industry Sector" is selected.
- 3) and, in the following, the relevant spERC scenario is selected.

During the last step, only those spERCs are displayed that fit to both the selected industry sector and the selected generic ERC scenario.

EasyTRA aggregates all wide dispersive use exposures from all scenarios for one substance at the end. Therefore, it is important that volumes released to the environment are not double counted or alternatives regarded as this may lead to a calculated higher environmental exposure that exceeds the volume that is actually manufactured.


In the "Expert" mode, an internal spERC generator is available (see chapter 5.5.1) with which individual conditions can be programmed if the exposure conditions for a specific application from the stored spERCs cannot be reflected. Scenarios which are generated by the spERC Generator (see Chapter 5.5.1) can only be loaded if

- 1) first, the corresponding generic ERC scenario is selected
- 2) in the field "spERC Industry Sector" the entry "User-defined spERC" is selected
- 3) and, in the following, the relevant spERC scenario is selected.

During the last step, only those user-defined spERCs are displayed that are assigned to the selected genericERC.

In the field "Sewage Treatment Plant", the discharge of waste water via either a communal sewage treatment plant (indirect discharger) or a direct discharge of contaminated waste water in surface water must be selected. Normally, waste water in Europe is treated, i.e. the standard setting should be "Sewage Treatment Plant = Check".

Via the field "spERC", the list of self-defined exposure scenarios which have been generated by the spERC Generator can be accessed.

The button  can be found at the end of every line of the "Environmental Assessment" input mask, which enables you to enter Tier 3 defaults. Refer to Chapter 5.4.2 for details.

Along with emission scenarios which define the release of the specified substance in the different environmental compartments, sediment, soil), the inherent characteristics of a substance also play an equally important role.

The first step is to define the biodegradability of a substance as this decisively influences the concentration of the substance in the environment (PEC = predicted environmental concentration).

The biodegradability according to the rating criteria of the EU Guideline 67/548/EG or GHS Regulation (EG)1272/2008 is a mandatory entry and must be included (via drop-down menu). If data is available, EasyTRA also enables individual degradability rate entries in this mask for different compartments, which might lead to more advantageous elimination rates (see Chapter 5.5.1).

Biodegradation rate [per day]

STP:	<input type="text"/>	default: 0.00	Surface water:	<input type="text"/>	default: 0.00
Soil:	<input type="text"/>	default: 0.00	Marine water:	<input type="text"/>	default: 0.00

The most valuable information regarding environmental exposure is, of course, the measured concentration in the environment. Especially in the the case of wide dispersive use of substances, the measured environmental concentration depicts the reality best. If you have representative measurement values, you can document them for every compartment in the Tier 2 box.. In these cases, EasyTRA calculates for regional (or alternatively local) emissions using your measurement values instead of with the simulated PEC values.

Measured Environmental Concentration

Surface water:	<input type="text" value="120.00"/>	µg/L	Use for local PEC	?
Freshwater sediments:	<input type="text" value="25.00"/>	µg/kg	Use for regional PEC	
Marine water:	<input type="text"/>	µg/L	Use for regional PEC	
Marine sediments:	<input type="text"/>	µg/kg	Use for regional PEC	
Soil:	<input type="text"/>	µg/kg	Use for regional PEC	

The ECHA guidelines require that the maximum tonnage for an environment scenario must be included if the exact amount that is used in the individual scenarios is unknown (worst-case approach). This means that should there be a very high numbers of cases, the substance volume that is seemingly released into the environment is very much higher than the actually produced substance volume. This results in an unrealistic influence on local emissions with high case numbers as EUSES standardly adds both the regional proportion of emissions of all scenarios and the local emissions of the individual scenarios. The regional proportions of releases are actually small, but in the sum of many worst-case scenarios, the local release can easily be greatly exceeded. This is unrealistic and is only the result of the aggregation of tonnages of all scenarios.

EasyTRA allows the restriction of background contamination to the actual worst case.

Easy Tra assumes that the total annually produced substance is released into the regions in the course of a year. In those cases where the EUSES concentration is higher than the worst-case, the resulting regional concentration is added to the local release of a scenario instead of the EUSES aggregated regional concentration. As the worst-case is based on the calculated total volume of the produced substance, this value can never be exceeded in practice.

If you would like to use the EasyTRA approach instead of the EUSES approach, enter the maximum total releasable tonnage in the corresponding field of the Tier 2 settings. The deviating basis of calculation will be documented in the EasyTRA report.

Further mandatory entries are the reference values of the specified substance. These so-called Predicted No Effect Concentrations (PNECs) are deduced from the available data regarding ecological toxicity. Please refer to the current ECHA “TECHNICAL GUIDANCE DOCUMENT FOR PREPARING THE CHEMICAL SAFETY ASSESSMENT” RIP 3.2-2, Chapter R.10 Environmental Hazard Assessment (especially Table R. 10-4 Assessment factors to derive a PNECaquatic) for further details. For a comprehensive environmental risk assessment, the PNEC values for all relevant compartments, i.e. sewage treatment (“Microorganisms in STP” which defines the chronic bacterial toxicity in sewage treatment sludge), freshwater, freshwater sediment, marine water, marine water sediment and soil should be available.

Manual entry of indicative reference values		Basis of reference value
Microorganisms in STP:	<input type="text"/> mg/L	PNEC
Freshwater aquatic:	<input type="text"/> mg/L	PNEC
Freshwater sediment:	<input type="text"/> mg/kg _{wwt}	PNEC
Marine water:	<input type="text"/> mg/L	PNEC
Marine sediment:	<input type="text"/> mg/kg _{wwt}	PNEC
Terrestrial compartment:	<input type="text"/> mg/kg _{wwt}	PNEC
Man via the environment (total daily intake):	<input type="text"/> mg/kg _{bw} /day	DNEL


The entry “Man via the environment“ secures the safe daily dosage for humans. Normally, it is identical with the oral reference value in the input mask “Human Health- Consumer”.

In the field “Anaerobic Degradation” you may enter data on the anaerobic degradation. Caution: This value only affects the aggregated exposure of all wide despersive use scenarios, but not on the exposure in local sediments.

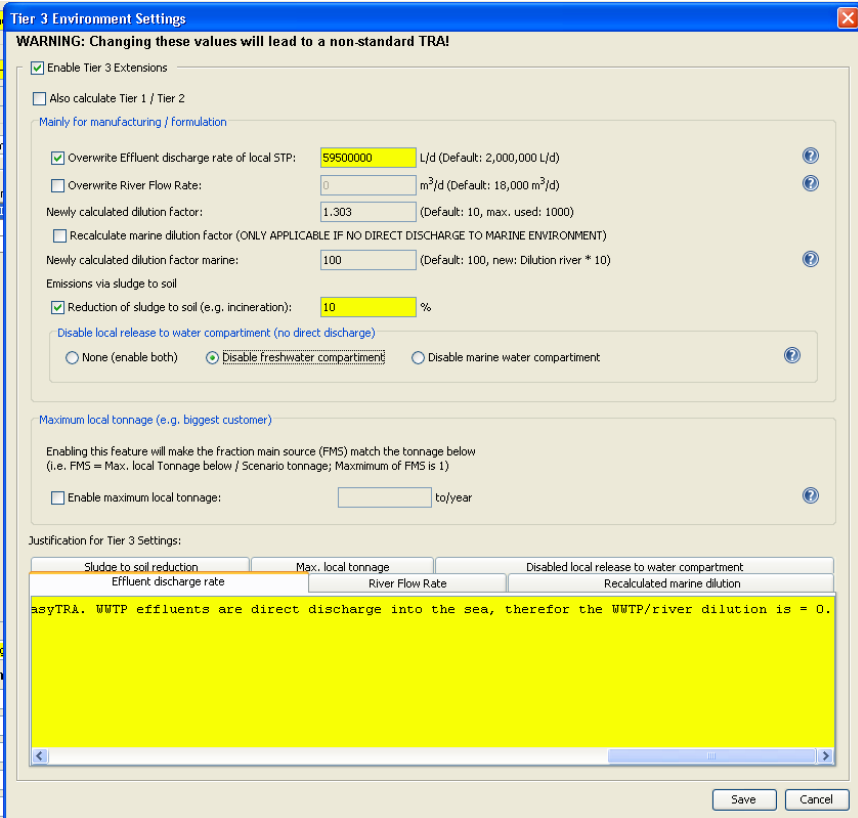
Anaerobic degradation:

5.4.2 Tier 3 Assessments

Tier 3 assessments are characterized by being customer or site specific.

The button  can be found at the end of every line of the “Environmental Assessment” input mask. This button only appears if at least one field of the scenario has been filled in. In order to carry out a Tier 3 calculation which deviates from defaults, a further input field can be opened. If the Tier 3 settings have been activated, the button will turn red to make it visible directly in the scenario overview.

The environmental assessment standardly assumes that the wastewater is discharged in a small communal sewage treatment plant (10,000 inhabitants) which lies on a small river (water flow rate 18,000 m³/day). These default values result in a dilution proportion of sewage treatment plant/river of 1:10. On the Tier 3 level, specific dilution factors can be entered between the sewage treatment plant and the river the water is discharged into. For “wide dispersive use” applications, this is not possible.



Tier 3 Environment Settings

WARNING: Changing these values will lead to a non-standard TRA!

Enable Tier 3 Extensions

Also calculate Tier 1 / Tier 2

Mainly for manufacturing / Formulation

Overwrite Effluent discharge rate of local STP: 59500000 L/d (Default: 2,000,000 L/d)

Overwrite River Flow Rate: 0 m³/d (Default: 18,000 m³/d)

Newly calculated dilution factor: 1.303 (Default: 10, max. used: 1000)

Recalculate marine dilution factor (ONLY APPLICABLE IF NO DIRECT DISCHARGE TO MARINE ENVIRONMENT)

Newly calculated dilution factor marine: 100 (Default: 100, new: Dilution river * 10)

Emissions via sludge to soil

Reduction of sludge to soil (e.g. incineration): 10 %

Disable local release to water compartment (no direct discharge)

None (enable both) Disable freshwater compartment Disable marine water compartment

Maximum local tonnage (e.g. biggest customer)

Enabling this feature will make the fraction main source (FMS) match the tonnage below (i.e. FMS = Max. local Tonnage below / Scenario tonnage; Maximum of FMS is 1)

Enable maximum local tonnage: to/year

Justification for Tier 3 Settings:

Sludge to soil reduction	Max. local tonnage	Disabled local release to water compartment
Effluent discharge rate	River Flow Rate	Recalculated marine dilution
asyTRA. WWTP effluents are direct discharge into the sea, therefore the WWTP/river dilution is = 0.		

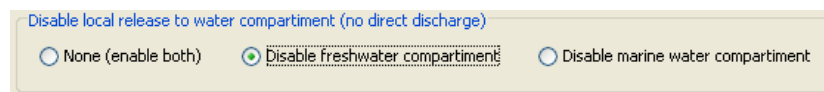
Save Cancel

The calculation of marine exposure is standardly based on the assumption that the release of a substance by the manufacturer/user into the ocean occurs directly, possibly upstream of a sewage treatment plant. EUSES presets an unchangeable dilution factor of 100, which is very restrictive. The corresponding $RCR_{\text{marinewatersediment}}$ therefore describes only local scenarios. The dilution effects for the release via a river or the actual dilution rate into the ocean is not taken into consideration. If you would like to calculate the wide (“regional”) effect on marine ecosystems while taking the dilution of a specific river into consideration, activate the selection box “New calculation Marine Dilution”. In this case, an

additional factor of 10 will be applied to the specific dilution of the river, which simulates the dilution of river water by the ocean. Depending on the specific dilution factor for the river, you can achieve a higher total dilution this way than the EUSES standardly sets (Factor 100). If there are no specific values for the dilution by the river, the marine water factor remains at 100.

Please observe that when “New calculation Marine Dilution” is activated a fundamentally different scenario is depicted compared to the normal $RCR_{\text{marinewatersediment}}$.

EasyTRA allows you to differentiate between the release in fresh water or marine water if direct emissions to one of these compartments does not occur (e.g. because the affected treatment plant emits directly into the ocean and not via a river). By clicking the respective button you can disable the respective compartment. In this case only the regional emissions to the “disabled” compartment are calculated.




EasyTRA must standardly assume that all sewage sludge is taken to fields and meadows as fertilizer. Many sewage treatment plants, however, dispose of their sewage treatment sludge in a different way. On the Tier 3 level, you can modify the whereabouts of the sewage sludge to the real situation by taking the reduction of produced sewage treatment sludge into account accordingly. If the sewage sludge is, for example, completely burned, the value in the entry field would be entered with the value “100”.

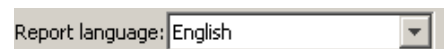
EasyTRA must standardly assume that the local emission is equal to the tonnage which you assign to the scenario in total (field: “Tonnage”) . In most cases this is, however, a cumulative value and the total tonnage is actually distributed over many places in Europe. The setting “maximum local” tonnage enables you to correct the overestimation of the local emission. A reasonable size would, for example, be the annual accepted volume of your biggest individual customer. Please observe that this setting has no influence on scenarios with wide dispersive use.

Important: As deviations from the defaults occur in Tier 3, which have been agreed upon between ECHA, EU member states and the industry, a justification absolutely must be saved as to why the use of Tier 3 standards are possible in this case. This justification is also output in the TRA report and CSR and is a part of the required documentation. **Therefore please only use the English language in this field.** The justifications for the various Tier-3 measures are distributed among different tabs.

6 TRA-Report

The button  enables you to generate a comprehensive report on the basis of the entered scenarios, which you can then save in a pdf format. Depending on the scope of the report, the output may take several seconds.

The output language of the report can be selected in the selection box.

A screenshot of a software interface showing a dropdown menu for selecting the report language. The text 'Report language:' is followed by a text box containing 'English' and a small downward-pointing arrow on the right side.

The output language need not be the same as in the input module (see Chapter O). Only English and German are currently available as report languages.

EasyTRA-generated reports may only be used by licensees. For this reason every EasyTRA Report includes a legal disclaimer and expressly names the licensee. For further information on the various types of licenses, please consult the EasyTRA webpage (www.easytra.de).

The report is similarly structured as the EasyTRA input module. It contains the calculated exposure scenarios for the three REACH relevant target areas: Consumer, Worker, and Environment. In the environmental compartment, emission volumes which are safe with reference to the substance inherent characteristics are additionally reported. Msafe gives information on the substance volume which is safely discharged into sewage per day in kilograms. Due to the different environmental boundary conditions, different Msafe values result for the individual compartments due to the primarily emitted substance volumes. The lowest Msafe value is always decisive for safe use.

Two appendices are included at the end of the report. Appendix I documents all of the entry values used. Individual entry values with justified deviations from TRA defaults are termed "Tier 2" or "Tier 3" (see above). Appendix II contains all of the defaults used and the calculation formulas. Appendix III documents programming errors in ECETOC® TRA 2010 (as of April 2010) that were corrected in EasyTRA. These changes lead to occasional deviations between ECETOC® TRA 2010 and EasyTRA risk assessments.

The individual results for the target groups are subdivided according to the exposure route (oral, dermal, inhalatory) or compartment (freshwater, marine water, sediment, soil).

The exposure for the different exposure routes and compartments, which is calculated by the EasyTRA entry values, is found in the unhighlighted fields of the report. The risk assessment

calculations (“risk characterization ratios” (RCRs)) are highlighted in color and are found to the right of these exposure values. These are calculated for every route and compartment by the quotient from exposure and the corresponding reference value. A RCR >1 (highlighted in red) indicates that the reference values have been exceeded and the use is therefore unsafe, while a RCR<1 (highlighted in green) indicates that the reference values fall below the prescribed limitation and are thus deemed safe. For humans, the total exposure from all routes is additionally assessed.

Risk Characterisation Ratio - Inhalation	Risk Characterisation Ratio - Dermal	Risk Characterisation Ratio - Total
0.501429	1.371	1.873
0.501429	0.274286	0.775714

The comparison between the default calculation and Tier 2 or Tier 3 calculations is particularly convenient. Here, you can immediately see how the Tier 2 or Tier 3 settings affect your scenario. If your scenario is not yet safe (=red), you can return to the input module and decide on new measures to make your scenario safe.

RCRs, that are marked “-“ have no exposure via the individual routes /compartments.

Certain parameter settings can, in rare cases, lead to conflicts in the calculation routine. These conflicts are marked in the TRA Report by the information “Check Input”. It is recommended to modify the scenario until the error message disappears.

A directory of all the abbreviations used are found at the end of the report.

You can generate an unlimited number of TRA Report versions, e.g. while you are optimizing scenarios. The Report Generator always calculates using the most current entry values. The “old” report versions remain as an independent document as long as EasyTRA (and, of course, the individual report) remains open.

Disclaimer:

Although the greatest care was taken while programming EasyTRA, we do not assume liability for or guarantee the accuracy of the calculations of EasyTRA.

Users of the software EasyTRA are fully responsible for their calculations. Jansen Systems GmbH is not liable for the use of EasyTRA.

Change history:

Update 1.02

- Automatic amendment of complementary environment scenarios for existing worker/consumer scenarios.
- CSR generator.
- Manual amendment of life cycle category "consumer" when importing DUCC consumer scenarios without "consumer" flag.
- Presetting standard gloves efficacy when importing DUCC scenarios.
- Failure report for import of DUCC files

Update 1.1

- Generating missing environmental scenarios
CSR Generator

Update 1.2

- Combination Exposures
- Improved import functions for DUCC Scenarios
- Error report for data import errors
- Amend missing environmental scenarios automatically

Update 2.0

- Simultaneous calculation RCR
- Introduction of Tier 2 modification "Anaerobic degradation"
Adapted import function (efficacy gloves, advanced Import functions)

Update 2.1

- Formula max. "tonnage to region" also takes ERC/SpERC settings into consideration
- Column "Scenario Subtitles" removed from environmental table
- Improved functionality:
 - Drag and Drop
 - Copy/Paste
 - Only fill selected lines
 - Column sorting function
- Introduction of selection boxes in import of scenarios from IUCLID Chapter 3.5
- Live calculation of all dependent environmental scenarios
- Introduction of Tier 2 setting "Measured Environmental Concentration"
- Introduction of Tier 2 setting "Substance in Preparation" for dermal exposure of workers
- Introduction of Tier 3 setting "Reduction of Sewage Treatment Sludge Emission in Soil"
- Introduction of Tier 3 setting "Maximum Local Tonnage"
- Introduction of Tier 2 setting "Overwrite Standard Settings for Consumer"
- PC/AC generator for user-defined PC/AC
- Introduction of general comment field in data import
- Export of "unknown" Sector of Uses according to IUCLID 5.2 as descriptor "SU0"
- Differentiation between fresh and saltwater emissions in Tier 3 settings
- Introduction of Help function
- Introduction of the function "Also Consider Max. Concentration in Substance in Preparation for Dermal Exposure"
- Import of unfiled PC/AC
- Additional data in IUCLID 5 export

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